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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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12/30/2003

Arindam Datta

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08/13/2008

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NEW YORK, NY 10036-4003

EXAMINER

COONEY, JOHN M

ART UNIT

PAPER NUMBER

1796

NOTIFICATION DATE

DELIVERY MODE

08/13/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

usptomailnyc@kslaw.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/749,742	<b>Applicant(s)</b> DATTA ET AL.	
	<b>Examiner</b> John Cooney	<b>Art Unit</b> 1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 March 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-114 is/are pending in the application.
- 4a) Of the above claim(s) 14-49 and 56-114 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 50-55 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> .                                  | 6) <input type="checkbox"/> Other: _____                          |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :20080715, 20070625, 20050805, 20041209, 20041103 .

***Election/Restrictions***

Applicant's election with traverse of Group I. in the reply filed on 3-27-08 is acknowledged. The traversal is on the ground(s) that search would not be burdensome. This is not found persuasive because requirement for restriction is maintained to be properly set forth and applicants have not adequately established why search of the groups of invention would not be burdensome .

The requirement is still deemed proper and is therefore made FINAL.

This application contains claims 14-49 and 56-114 drawn to an invention nonelected with traverse in the reply filed on 3-27-08. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "biodurable" in claims 2 and 4 is a relative term which renders the claim indefinite. The term "biodurable" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It can not be

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determined what degree of bio-resiliency is intended to be encompassed by the claimed term "biodurable".

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-13 and 50-55 are rejected under 35 U.S.C. 102(b) as being anticipated by Brady et al. {2002/0072550}.

Brady et al. discloses preparations of reticulated/porous, biostable, polycarbonate based polyurethane elastomeric materials based on isocyanates as claimed reading on the preparations of applicants' claims (see abstract, drawings, paragraphs [0005]-[115], and examples, as well as, the entire document). Though Brady et al. does not specify the ranges of recovery and compressibility values of applicants' claims, it does provide for composition that are not seen to differ in make-up from the compositions claimed, and it provides that its formed articles have good integrity such that it is held that these features are inherent to the products having high

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compressibility and high recoverability disclosed by Brady et al. Based on the drawings, the void content, and overall make-up of the compositions of Brady et al., it is held that the pore diameters of applicants' claims are inherent to the teachings of Brady et al.

Claims 1-2, 4-13, 50-55 are rejected under 35 U.S.C. 102(b) as being anticipated by WO-01/74582 {WO-'582}.

WO-'582 discloses preparations of reticulated/porous, biostable, elastomeric materials as claimed reading on the preparations of applicants' claims (see abstract, pages 1-3, 1—16, 21-22, and examples, as well as, the entire document). Though WO-'582 does not specifically identify the specific ranges of recovery and compressibility values as claimed by applicants, it does provide for composition that are not seen to differ in make-up from the compositions claimed, and it provides that its formed articles have good strength properties such that it is held that these features are inherent to the products having high compressibility and high recoverability disclosed by WO provides for void make-up and sizes meeting those of applicants' claims.

Claims 1-2, 4-13, 50, and 54-55 are rejected under 35 U.S.C. 102(b) as being anticipated by Vyakarnam et al. {6,306,424}.

Vyakarnam et al. discloses preparations of reticulated/porous, biostable, elastomeric materials as claimed reading on the preparations of applicants' claims (see abstract, drawings, see column 4 line 51 – column 11 line 25, and examples, as well as,

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the entire document). Though Vyakarnam et al. does not specifically identify the specific ranges of recovery and compressibility values of applicants' claims, it does provide for composition that are not seen to differ in make-up from the compositions claimed, and it provides that its formed articles have good strength properties (see again column 11 lines 13-25) such that it is held that these features are inherent to the products having high compressibility and high recoverability disclosed by Vyakarnam et al. Based on the drawings, the void make-up defined, and overall make-up of the compositions of Vyakarnam et al., it is held that the pore diameters of applicants' claims are inherent to the teachings of Vyakarnam et al.

Claims 1-2, 4-13, 50, and 54-55 are rejected under 35 U.S.C. 102(b) as being anticipated by Vyakarnam et al. {6,306,424}.

Vyakarnam et al. discloses preparations of reticulated/porous, biostable, elastomeric materials as claimed reading on the preparations of applicants' claims (see abstract, drawings, see column 5 lines 37 – column 11 lines 46, and examples, as well as, the entire document). Though Vyakarnam et al. does not specifically identify the specific ranges of recovery and compressibility values of applicants' claims, it does provide for composition that are not seen to differ in make-up from the compositions claimed, and it provides that its formed articles have good strength properties (see again column 11 lines 35-46) such that it is held that these features are inherent to the products having high compressibility and high recoverability disclosed by Vyakarnam et

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al. Based on the drawings, the void make-up, and overall make-up of the compositions of Vyakarnam et al., it is held that the pore diameters of applicants' claims are inherent to the teachings of Vyakarnam et al.

Claims 1-4, 9-13 and 50-55 rejected under 35 U.S.C. 102(b) as being anticipated by WO99/24084 {WO-'084}.

WO-'084 discloses preparations of porous, biostable, polycarbonate based polyurethane elastomeric materials reading on the preparations of applicants' claims (see pages 4 & 5 and claims, as well as, the entire document). WO-'084 provides for use of isocyanates as claimed. Though WO-'084 does not specify the ranges of recovery and compressibility values of applicants' claims, it does provide for composition that are not seen to differ in make-up from the compositions claimed, and it provides that its formed articles have high recoverability and high compressibility. Accordingly, it is held that these features are inherent to the products having high compressibility and high recoverability disclosed by WO-'084.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.



Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO-'582 as applied to claims 1, 2, 4-13, and 50-55 above, and further in view of Brady et al. {2002/0072550}.

WO-'582 differs from the claims in that it does not specify polycarbonate components/reactants in the making of its polyurethanes. However, Brady et al. discloses polycarbonate polyurethane materials to be useful for the purpose of providing good biostable implantable urethane products. Accordingly, it would have been obvious for one having ordinary skill in the art to have employed the polycarbonate polyurethane forming materials disclosed by Brady et al. as the polyurethane forming materials used in WO-'582 for the purpose of producing acceptable biostable, implant materials in order to arrive at the products of applicants' claims with the expectation of success in the absence of a showing of new or unexpected results.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory

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double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-13 and 50-55 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-101 of copending Application No. 11/652,763. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending claims are directed towards preparations which overlap in structure and make-up with the instant claims such that operation within the controls of its disclosure for the purpose of providing acceptable implantable articles would have been obvious to one having ordinary skill in the absence of a showing of new or unexpected results attributable to differences in the claims. At least claim 1 of the instant claims is fully encompassing of claim 1 of the copending claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-13 and 50-55 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6,8-22, 41-46, and 89-141 of copending Application No. 10/848,624. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending claims are directed towards preparations which overlap in structure and

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make-up with the instant claims such that operation within the controls of its disclosure for the purpose of providing acceptable implantable articles would have been obvious to one having ordinary skill in the absence of a showing of new or unexpected results attributable to differences in the claims. At least claim 1 of the instant claims is fully encompassing of claim 1 of the copending claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Hirai et al. is cited for its disclosure of other benefits associated with the use of polycarbonate polyols in urethane synthesis operations.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Cooney whose telephone number is 571-272-1070. The examiner can normally be reached on M-F from 9 to 6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck, can be reached on 571-272-1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/John Cooney/

Primary Examiner, Art Unit 1796